Actions Taken by FDA Center for Veterinary Medicine

The following corrections or additions to the list were published in the Federal Register in December 2013.

Original Approvals

This section displays the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

ANADA Number: 200-432

Trade Name:	NexHA™
Pioneer:	Legend® Injectable Solution
Ingredients:	Hyaluronate sodium
Sponsor:	Bioniche Animal Health USA, Inc.
Approval Date:	October 18, 2013
Status:	Rx
Route:	Intra-articular or intravenous injection
Species:	Horses
Drug Form:	Injectable solution
Concentration:	10 mg/ml
Indications:	Treatment of joint dysfunction of the carpus or fetlock in horses due to non-infectious synovitis associated with equine osteoarthritis.

21 522.1145 *78 FR 73697-73698*

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval, please refer to 21 CFR Parts 500 and the related Federal Register notices.

NADA Number: 141-251

Trade Name:	Advantage Multi® for Dogs
Ingredients:	Imidacloprid and Moxidectin
Sponsor:	Bayer HealthCare LLC, Animal Health Division
Approval Date:	October 24, 2013

This supplement provides for the treatment of *Dirofilaria immitis* circulating microfilariae in heartworm-positive dogs and the treatment and control of sarcoptic mange caused by *Sarcoptes scabiei* var. *canis*.

21 CFR 524.1146 *78 FR 73697-73698*

NADA Number: 141-254

Trade Name:	Advantage Multi® for Cats
Ingredients:	Imidacloprid and Moxidectin
Sponsor:	Bayer HealthCare LLC, Animal Health Division
Approval Date:	October 31, 2013

This supplement provides for the prevention of heartworm disease in ferrets caused by *Dirofilaria immitis*; kills adult fleas (*Ctenocephalides felis*) and is indicated for the treatment of flea infestations on ferrets.

21 CFR 524.1146 *78 FR 73697-73698*

Sponsor Change

NADA Number: 141-255

Previous: Eka Chemicals, Inc.

New Sponsor: Western Chemical, Inc.

Drug Labeler Code: 050378

21 CFR 529.1150 *78 FR 73697-73698*

Withdrawal of Approval

NADA Number: 005-414

Sponsor: Zoetis Inc.
Trade Name: Ren-O-Sal® Tablets
Ingredients: Roxarsone

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 520.2088 *78 FR 78716*

NADA Number: 006-019

Sponsor: Zoetis Inc.
Trade Name: Zoco Poultry Tablets
Ingredients: Roxarsone

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 520.2088 *78 FR 78716*

NADA Number: 006-081

Sponsor: Zoetis Inc.
Trade Name: Korum Improved Formula
Ingredients: Roxarsone

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 520.2089 *78 FR 78716*

NADA Number: 008-274

Sponsor: Zoetis Inc.
Trade Name: Pig Scour Tablets
Ingredients: Roxarsone

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 520.2088 *78 FR 78716*

NADA Number: 093-025

Sponsor: Zoetis Inc.
Trade Name: 3-Nitro® Soluble
Ingredients: Roxarsone

This product is withdrawn because the product is no longer manufactured or marketed.

21 CFR 520.2087 *78 FR 78716*

Suitability Petitions

Number: 13-P-0426-0001

Petitioner: Shotwell & Carr, Inc.
Date Filed: April 22, 2013
Action: Approved
Action Date: August 1, 2013
Description: The petitioner requests to file an ANADA for a generic cyclosporine oral solution that differs from the pioneer product, ATOPICA gelatin capsule, sponsored by Novartis Animal Health US under NADA 141-218. The generic product will differ in dosage form. The RLNAD is approved as gelatin capsules (10% w/w) and the proposed generic product is an oral solution (10% w/w).

Number: 13-P-0632-0001

Petitioner: Piedmont Animal Health
Date Filed: May 24, 2013
Action: Approved
Action Date: July 19, 2013
Description: The petitioner requests to file an ANADA for a generic deracoxib formed soft chewable tablet that differs from the pioneer product, DERAMAXX Chewable Tablets, sponsored by Novartis Animal Health US, Inc. under NADA 141-203. The generic product will differ in dosage form. The RLNAD is approved as a compressed tablet and the proposed generic product is a formed soft chewable tablet.

Number: 13-P-0996-0001

Petitioner: Piedmont Animal Health
Date Filed: August 13, 2013
Action: Approved
Action Date: December 9, 2013
Description: The petitioner requests to file an ANADA for a generic cefpodoxime proxetil tablet that differs from the pioneer product, SIMPLICEF tablets, sponsored by Zoetis Inc. under NADA 141-232. The generic product will differ in dosage form. The RLNAD is approved as a film-coated tablet and the proposed generic product is a formed soft chewable tablet.

Number: 13-P-1101-0001

Petitioner: Piedmont Animal Health
Date Filed: May 22, 2013
Action: Approved
Action Date: November 18, 2013
Description: The petitioner requests to file an ANADA for a generic clindamycin hydrochloride tablet that differs from the pioneer product, ANTIROBE Capsules, sponsored by Zoetis Inc. under NADA 120-161. The generic product will differ in dosage form. The RLNAD is approved as a capsule available in 25 mg, 75 mg, 150 mg, and 300 mg capsule strengths. The proposed generic product is a soft chewable tablet that will be available in the same strengths as the pioneer.

Number: 13-P-1078-0001

Petitioner: Parnell Technologies Pty Ltd.
Date Filed: September 3, 2013
Action: Denied
Action Date: December 11, 2013
Description: The petitioner requests to remove the intravenous route of administration from their approved ANADA 200-541, GONABREED (gonadorelin acetate) injectable solution. The approved generic product and the pioneer product, CYSTORELIN Injectable Solution, sponsored by Merial Ltd. under NADA 098-379, are currently both approved for intravenous and intramuscular administration.